

DEC 13 1996

510(k) Summary

K964749

Trade Name: Coverage HBV

Common/Usual Name: General Purpose Disinfectant

Submitter/Manufacturer: ConvaTec, Division of E.R. Squibb and Sons, Inc.
5035 Manchester Avenue
St. Louis, MO 63110
Establishment Registration Number: 1940768

Contact: Mike Ebers, Manager Regulatory Affairs (314) 535-1390

Description: Coverage HBV is a liquid chemical germicide utilizing quaternary ammonium chloride compounds as active ingredients.

Intended Use: Coverage HBV is used to inactivate specific bacteria, fungi and viruses on hard inanimate surfaces including reusable non-critical medical devices and environmental surfaces in healthcare facilities.

Substantial Equivalence to: (1) Tor Germicidal Cleaner, Huntington Laboratories, (2) Quat-Syl 256, National Laboratories, (3) Futron 25, Hysan Corp.

Comparison to Listed Substantially Equivalent Products: Listed products are also liquid chemical germicides utilizing quaternary ammonium chloride compounds as active ingredients to inactivate specific bacteria, fungi, and viruses on hard inanimate surfaces.

Safety Data: Acute Oral LD₅₀ (Rats) = 5,000 mg/kg
Acute Dermal LD₅₀ (Rabbits) = 2,000 mg/kg
Dermal Irritation (Rabbit) neat = Corrosive. Direct contact can cause moderate to severe redness and swelling.
Eye Irritation (Rabbit) neat = Severe nonreversible irritation.
Eye Irritation (Rabbit) 1:64 aqueous dilution = No irritation
Dermal Sensitization (Guinea Pig) = Negative as sensitizer

Effectiveness Data: Germicidal: Approved by EPA as effective against *S. aureus*, *S. choleraesuis* and *Ps. aeruginosa* and other bacteria.

Fungicidal: Approved by EPA as effective against *T. mentagrophytes*. Also *Aspergillus candidus*, *Aspergillus niger*, *Candida albicans*, *Penicillium chermesinum*, *Penicillium oxalicum*, *Penicillium spinulosum* and *Ulocladium* sp.

Virucidal: Approved by EPA as effective against Avian Influenza/Turkey/Wisconsin Virus, Cytomegalovirus, Hepatitis B Virus, Herpes Simplex type 1 and type 2 Virus, Influenza A Virus, Influenza B Virus, Influenza C Virus, Measles Virus, Newcastle Disease Virus, Parainfluenza type 1 Virus, Poliovirus type 1, Porcine Parovirus, Pseudorabies Virus, T1 bacteriophage, T4 bacteriophage and Vaccinia.